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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/092,411 | 08/22/2002 | Lynn A. Doucette-Stamm | 032796-101 (GTC02-01A) | 9046 |
| 7590 01/30/2004 | | | | |
| Tercsa Stanek Rea BURNS, DOANE, SWECKER & MATHIS, L.L.P. P.O. Box 1404 Alexandria, VA 22313-1404 | | | EXAMINER KIM, YOUNG J | |
| | | | ART UNIT 1637 | PAPER NUMBER |

DATE MAILED: 01/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/092,411

Applicant(s)

DOUCETTE-STAMM ET AL.

Examiner

Young J. Kim

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1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-28 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: ____

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-10 and 24, drawn to an isolated nucleic acid, fragment thereof, a recombinant vector comprising the nucleic acid, a host cell comprising the recombinant vector, a method of using the nucleic acid to express its protein, a method of detecting the presence of the nucleic acid, and a probe, classified in class 536, subclass 23.7.
- II. Claims 11-16, drawn to a vaccine comprising the nucleic acid and a method of using the vaccine to treat *S. epidermis* infection, classified in class 424, subclass 9.2.
- III. Claim 17, drawn to a *S. epidermis* polypeptide, classified in class 530, subclass 300.
- IV. Claims 18-23, drawn to a vaccine and a method for using the vaccine to treat *S. epidermis* infection, classified in class 424, subclass 184.1.
- V. Claims 25-28, drawn to a computer readable medium comprising a group of nucleic acid sequences, a computer system comprising a data storage comprising the group of nucleic acid sequences, and methods of using the computer system, classified in class 702, subclass 19.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different

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functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the isolated nucleic acid, a vaccine comprising the nucleic acid, a polypeptide, and a vaccine comprising the polypeptide comprise different structures and therefore have different modes of operation. For example, the nucleic acid of Group I is structurally different from the polypeptide of Group III and is not required for the vaccine of Group IV. Further the nucleic acid of Group I involve different modes of operation and comprises different functions which are not useable together. For example, the nucleic acid of Group I already contains the method of using the nucleic acid to express its encoding polypeptide as well as a method of detecting the presence of the nucleic acid by hybridization. Such methods are not usable together with a method of treating an infection via use of vaccine (Group II), demonstrating that the products are clearly unrelated, rendering the search of the different product non-coextensive. With regard to the polypeptide of Group III, the product is structurally different from the nucleic acid of Group I, thus not useable together. The vaccine of Group II also does not require the polypeptide of Group III, resulting in searches which are not coextensive. Although the vaccine of Group IV comprises the polypeptide of Group III, the two products are deemed to be unrelated because the vaccine of Group IV requires that it produce a therapeutic effect (inherent to the use of the description, "vaccine"). This is evident in the method claim encompassed in Group IV, wherein the vaccine is used to *treat* an infection. Such intended use would require searches in the status of prior art, enablement purposes, etc, which are not coextensive in scope with a polypeptide. Group V is unrelated to Groups I-IV because the computer readable medium and a system is not useable together with the physical products of Groups I-IV. Such distinct uses are also clearly demonstrated in the

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methods encompassed in Group V, wherein the methods involve searching an electronic database in a computer system.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Sequence Election Requirement Applicable to Groups I-IV

In addition, Groups I-IV detailed above read on patentably distinct sequences. Each sequence is patentably distinct because they are unrelated sequences, and a further restriction is applied to Groups I-IV. For an elected Group, Applicants must further elect a single amino acid or nucleotide sequence.

Examination will be restricted to only the elected sequence.

A telephone call was not made to request an oral election to the above restriction requirement due to the complex nature of the requirement (MPEP § 812.01).

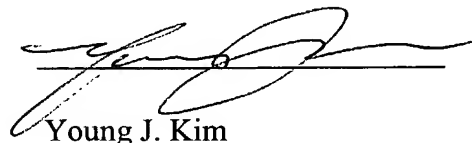
Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is not longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

A fully responsive communication will contain both a proper election of a group, and a single SEQ ID Number.

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (703) 308-9348 **(effective January 14, 2004, changed to 571-272-0785)**. The Examiner can normally be reached from 8:30 a.m. to 6:00 p.m. Monday through Thursday. If attempts to reach the Examiner by telephone are unsuccessful, the Primary Examiner in charge of the prosecution, Dr. Kenneth Horlick, can be reached at (703)-308-3905 **(effective January 14, 2004, changed to 571-272-0784)**. If the attempts to reach the above Examiners are unsuccessful, the Examiner's supervisor, Gary Benzion, can be reached at (703) 308-1119. Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. All official documents must be sent to the Official Tech Center Fax number: (703) 872-9306. For Unofficial documents, faxes can be sent directly to the Examiner at (703) 746-3172 **(effective January 14, 2004, changed to 571-273-0785)**. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Young J. Kim
Patent Examiner
Art Unit 1637
1/27/04